REMARKS

The Examiner is thanked for her courtesies extended to the undersigned during the August 12, 2002 telephone interview.

Claims 31-49 are pending in the present application and claims 31, 38, 41 and 42 are amended. The amendments to claim 31, 38, 41 and 42 involve correcting informalities and claim dependency and do not raise any issue of new matter. The amendments to claims 31, 41 and 42 also does not raise any new issues. Moreover, Applicant believes that the amendment places the present application in condition for allowance or for an appeal. Therefore, entry of the present Amendment is respectfully requested. Upon entry of the present Amendment, claims 31-49 will be under examination. Applicant has concurrently filed a notice of appeal with the Board of Appeals and Interferences.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 31-41 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Specifically, the Office Action asserts that "the specification and the claims as originally filed do not provide a clear support for 'wherein the administration of bee venom and anesthetic reduces visual analog scale of the patient by at least 57" in claim 31.

Applicant respectfully disagrees with this ground of rejection as the present application fully described the use of bee venom and anesthetic to reduce the pain of the patient by at least 57 on a visual analog scale. Specifically, example 2 describes a reduction in the pain of a patient by 57 (or 73 minus 16) on a visual analog scale after treatment with the claimed method. Examples 1, 3-8 show the reduction in the pain of the patient by 83, 75, 65, 65, 80, 78 and 72, respectively on a visual analog scale. These examples further support the conclusion that Applicant had possession of the claimed method at the time the application was filed. Therefore, claims 31-41 satisfy the requirements of 35 U.S.C. § 112, first paragraph and reconsideration and withdrawal of this rejection are respectfully requested.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 31-41 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office Action objects to the use of the

phrases "reduces visual analog scale of the patient by at least 57" in claim 31 and "reduces visual analog scale of the patient to 28 or less" in claim 41

Applicant respectfully points out that these two phrases are rewritten as "reduces the pain of the patient by at least 57 on a visual analog scale" in the amended claim 31 and " reduces the pain of the patient to 28 or less on the visual analog scale" in the amended claim 41. Applicant notes that visual analog scale is generally used in the art to define pain, see for example, Churchill Livingston, Text Book of Pain, New York, 3rd Edition (1994), pp. 338-339 and in Lea and Febiger, The Management of Pain, Philadelphia, 2nd Edition (1990), pp. 581-582. Therefore, claims 31-41, as amended, are not indefinite as the use of visual analog scale to measure patient's pain in the claimed methods delineates the metes and bounds of the claims. Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

Rejection Under 35 U.S.C. § 102(b)

Claims 31-37, 39 and 41 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Steigerwaldt et al. Specifically, the Office Action asserts that Steigerwaldt discloses, on page 1047, column 1, "administration of an anesthetic, such as procaine hydrochloride in an amount of 0.2% or 0.2 mg per injection, which is about 0.1 mg to about 0.3 mg per injection." *Office Action at 7.*

As stated during the August 9, 2002 telephone interview between Examiner Huynh and the undersigned, Applicant believes that these claims are rejected improperly because both the interpretation of Steigerwaldt by the Patent Office and its conclusion with regard to this rejection are incorrect. Specifically, Steigerwaldt discloses the use of "procaine hydrochloride 0.2% as a local anesthetic." It cannot be interpreted as injecting 0.2% of procaine hydrochloride together with the standard bee venom simply because Steigerwaldt is silent on the mode of administration of procaine hydrochloride. In fact, the procaine hydrochloride can be administered by injection or by topical application or by both injection and topical application.

Even assuming that Steigerwaldt teaches the injection of 0.2% procaine hydrochloride, it does not disclose the amount of procaine hydrochloride being used in each injection. The disclosure of injecting "0.1cc standard bee venom" cannot be interpreted as injecting 0.1cc standard bee venom in a 0.2% of procaine hydrochloride solution as nothing teaches or suggests such a solution. The term "standard bee venom," as defined in Steigerwaldt

does not include 0.2% procaine hydrochloride in it. An injection of "0.1cc standard bee venom" just means an injection of "0.1cc standard bee venom" and nothing else.

Therefore, the interpretation of Steigerwaldt by the Patent Office is incorrect and a properly interpreted Steigerwaldt would not anticipate claims 31-37, 39 and 41 of the present application as Steigerwaldt does not disclose each and every element of any of these claims. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Rejection Under 35 U.S.C. § 103(a)

Claims 31 and 38 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Steigerwaldt in view of Cerrati et al., Alternative Complementary Therapies, Pages 57-58 ("Cerrati").

Applicant respectfully traverses this rejection as the Patent Office does not articulate where in the prior art are there any teaching, suggestion or motivation that Steigerwaldt can be combined with Cerrati to obtain the claimed invention. Applicant notes that the "suggestion or motivation" requirement must be satisfied from the disclosure of the prior art reference or from the knowledge of persons skilled in the art, (see M.P.E.P. § 2143.01) not by the use of hindsight in view of the present application (emphasis added). In this case, the Patent Office, at a minimum, fails to carry its burden to show that it has satisfied "suggestion or motivation" requirement for combining Steigerwaldt and Cerrati.

Even assuming that Steigerwaldt can be combined with Cerrati, the combination does not teach or suggest "all the claim limitations" of claims 31 and 38. Specifically, Steigerwaldt does not teach or suggest the use of an anesthetic in an amount of 0.1 to 0.3 mg per injection. Nor does Steigerwaldt teach or suggest the use of such a small amount of anesthetic to "reduce the pain of the patient by at least 57 on a visual analog scale." Cerrati does not remedy the deficiencies of Steigerwaldt as Cerrati also does not teach or suggest these features of claims 31 and 38. Therefore, it is respectfully contended that the Office Action fails to establish a *prima facie* case of obviousness under the standard of M.P.E.P. § 2142.

In addition, the claimed method achieved unexpected results of treating severe pain using a combination of between 0.01 mg and about 1.0 mg per injection of bee venom and between 0.1 and 0.3 mg per injection of anesthetic. As stated in M.P.E.P. §716.02(a), "evidence of unexpected advantageous properties, such as superiority in a property the claimed compound shares with the prior art, can rebut *prima facie* obviousness." In this case, the unexpected results of the claimed methods can also rebut the obviousness rejection.

Therefore, Claims 31 and 38 are nonobvious over the combination of Steigerwaldt and Cerrati. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Rejection Under 35 U.S.C. § 103(a)

Claim 40 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Steigerwaldt in view of Cerrati and further in view of U.S. Patent No. 6,029,863 (the '863 patent") or Pharmaceutical Formulary.

Applicant contends that the Patent Office fails to carry its burden to show that there is teaching, suggestion or motivation in the prior art to combine Steigerwaldt with Cerrati. The Patent Office also fails to show there is teaching, suggestion or motivation in the prior art to combine Steigerwaldt, Cerrati and the '863 patent or Pharmaceutical Formulary.

As stated in applicant's response to the 103(a) rejection of claim 38, the combination of Steigerwaldt and Cerrati does not teach or suggest the use of an anesthetic in an amount of 0.1 to 0.3 mg per injection. Nor does the Steigerwaldt-Cerrati combination teach or suggest the use of such a small amount of anesthetic to "reduce the pain of the patient by at least 57 on a visual analog scale." Neither the '863 patent nor Pharmaceutical Formulary remedies the deficiencies of the Steigerwaldt-Cerrati combination. Applicant contends that the Office Action fails to establish a *prima facie* case of obviousness under the standard of M.P.E.P. § 2142 against claim 40.

Moreover, the claimed methods achieved unexpected results of relieving severe pain using a combination of between 0.01 mg and about 1.0 mg per injection of bee venom and between 0.1 and 0.3 mg per injection of anesthetic.

With regard to the Office Action's assertion that "Steigerwaldt et al teach the use of anesthetic and bee venom to reduce pain associated with rheumatoid arthritis as discussed supra and the reference treatment inherently reduces visual analog scale of the patient by at least 57," applicant would like to point out that the Board of Patent Appeals and Interference held in *ex parte Schricker*, 56 USPQ2d 1723 (Bd. Pat. App. & Int., 2000) that "inherency and obviousness are somewhat like oil and water - they do not mix well." The Board further stated that "when an examiner relies on inherency, it is incumbent on the examiner to point to the 'page and line' of the prior art which justifies an inherency theory." In this case, the Office Action does not points to the "page and line" of Steigerwaldt to justify an inherency theory on the reduction of pain by at least 57 on a visual analog scale.

Therefore, claim 40 is nonobvious over the combination of Steigerwaldt and Cerrati and the '863 patent or Pharmaceutical Formulary. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Rejection Under 35 U.S.C. § 103(a)

Claims 42-49 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Steigerwaldt in view of Banks et al., Chemistry and Pharmacology of Honey-bee venom ("Banks").

As stated in Applicant's response to the obviousness rejection of claims 31 and 38, Steigerwaldt does not disclose the use an anesthetic in an amount of 0.1 to 0.3 mg per injection to reduce the pain of a patient by at least 57 on a visual analog scale. Banks does not remedy the deficiencies of Steigerwaldt. Moreover, applicant achieves unexpected results of treating severe pain using a combination of between 0.01 mg and about 1.0 mg per injection of bee venom and between 0.1 and 0.3 mg per injection of anesthetic.

Therefore, claims 41-49 are nonobvious over the combination of Steigerwaldt and Banks and this ground of rejection should be reconsidered and withdrawn.

CONCLUSION

In view of the remarks and the claimed amendments, Applicant believes that the present application is in condition for allowance. Further and favorable considerations and the issuance of a Notice of Allowance with regard to claims 31-49 are earnestly solicited.

No fee, other than the $55.00 fee for a one-month extension of time for a small entity, is deemed necessary in connection with the filing of this Amendment. However, if any other fees are required, the Examiner is authorized to charge such fees to our Deposit Account No. 12-1095.

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Respectfully submitted,

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MARKED-UP COPY OF AMENDED CLAIMS:

31. (TWICE AMENDED) A method of reducing pain by administering bee venom to a patient in need of such treatment comprising the steps of:

administering to a patient, simultaneously or consecutively, (1) between about 0.01 mg and about 1.0 mg per injection of bee venom intradermally, subcutaneously or intramuscularly and (2) at least one anesthetic in an amount of about 0.1 mg to about 0.3 mg per injection, intradermally, subcutaneously or intramuscularly so as to reduce the irritation associated with the injection of bee venom, wherein the administration of the bee venom and anesthetic reduces the pain ~~visual analog scale~~ of the patient by at least 57 on a visual analog scale.

38. (TWICE AMENDED) A method of reducing pain by administering bee venom to a patient in need of such treatment comprising the steps of:

administering to a patient, simultaneously or consecutively, (1) between about 0.01 mg and about 1.0 mg per injection of bee venom intradermally, subcutaneously or intramuscularly and (2) at least one anesthetic in an amount of about 0.1 mg to about 0.3 mg per injection, intradermally, subcutaneously or intramuscularly so as to reduce the irritation associated with the injection of bee venom, wherein the administration of the bee venom and anesthetic reduces the pain of the patient by at least 57 on a visual analog scale; ~~The method of claim 31,~~ wherein said patient is suffering from a condition selected from the group consisting of Osteoarthritis, Gouty Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Fibromyalgia, Fibromyositis, Myofascial Dysfunction Pain Syndrome, Tennis Elbow and Golfers Elbow, Frozen Shoulder, Bursitis, Tendonitis, Chronic Surgical Inflammation of Soft and Bony Tissue, Peripheral Neuritis, Migraine, Eczema, Psoriasis, Multiple Sclerosis, Lupus.

41. (TWICE AMENDED) The method of claim 31, wherein the administration of the bee venom and the anesthetic reduces the pain ~~visual analog scale~~ of the patient to 28 or less on the visual analog scale.

42. (TWICE AMENDED) A method of administering bee venom to a patient in need of such treatment comprising the steps of:

administering to a patient, simultaneously or consecutively, (1) between about 0.01 mg and about 1.0 mg per injection of bee venom intradermally, subcutaneously or intramuscularly and (2) at least one anesthetic in an amount of about 0.1 mg to about 0.3 mg per injection, intradermally, subcutaneously or intramuscularly, wherein the bee venom comprises

about 40%-50% of melittin, or about 1.5-2.0% of hyaluronidase in dry weight, or wherein the bee venom exhibits about 40 to about 100HHU/mL of Hyaluronidase activity when diluted to 100mcg/mL, or is capable of inhibiting gelatin induced aggregation of erythrocytes of about 3-5mm/H; wherein the administration of said anesthetic reduces the irritation associated with the injection of bee venom; wherein the administration of the bee venom and anesthetic reduces the pain ~~visual analog scale~~ of the patient by at least 57 on a visual analog scale.